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Guidance for the Reregistration of Manufacturing-Use and Certain End-Use Pesticide Products Containing Ethoprop (041101) as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS CONTAINING ETHOPROP (041101) AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
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This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Note: Appendices V-1, V-5 and V-6 are not germane to this document and are not included.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), as amended in 1978, directs the Environmental Protection Agency (EPA) to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth certain of the requirements for registration and reregistration of all manufacturing-use products (MPs) containing the subject chemical as the sole active ingredient. These requirements include: that certain scientific data be submitted and that certain standards of toxicity, composition, labeling, and packaging be met. Registrants of MPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document and with the requirements contained in subsequent information from EPA about compliance with certain data support requirements.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

This guidance document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (the Agency) on registered manufacturing-use products (MPs) containing the soil insecticide-nematicide, ethoprop. The Agency's position is based on a consideration of available data for all currently registered uses and registered MPs with ethoprop as the sole active ingredient. This position is based on a number of considerations. The Standard considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by FIFRA Section 24(c), as well as Federal registrations granted or pending under FIFRA Section 3. Finally, the Agency sets forth the data requirements that must be met to register products covered by this document.

This Standard only addresses registration requirements for current or substantially similar future MPs and their intermediaries. Ethoprop MPs that differ appreciably from those described here may require amendments to the Standard. End-use products (EPs) will be registered under a separate Label Improvement Program.

B. CHEMICAL DESCRIPTION AND USE PROFILE

Ethoprop is the acceptable common name for O-ethyl S,S-dipropyl phosphorodithioate as determined by the American National Standards Institute (ANSI). The compound is recognized by the British Standards Institution and the International Organization for Standardization by the name of "Ethoprophos." The pesticidal uses of ethoprop were developed by the Virginia-Carolina Chemical Corporation and subsequently by Mobil Chemical Company; all registrations now are held by Rhone-Poulenc, Inc. Ethoprop is marketed currently or formerly under the names Mocap®, Jolt®, prophos (obsolete), and VC9-104. The Chemical Abstracts Registry (CAS) number for ethoprop is 13194-84-4, and the EPA Chemical Code number is 041101. Ethoprop is a clear yellow tinted liquid with a strong mercaptan odor. The empirical formula is $C_8H_{19}O_2PS_2$ and the molecular weight is 242.307. The boiling point is 86-91°C at 0.2 mmHg. Ethoprop is soluble in water to 750 ppm and soluble in most organic solvents.

There is one registered manufacturing-use product consisting of the technical grade of ethoprop (94%), and five federally registered end-use products containing ethoprop as the sole

active ingredient. These EP formulations are granules (5%, 10%, and 15%) and an emulsifiable concentrate (6 lb/gallon).

There are two federally registered end-use products containing ethoprop in combination with another insecticide, disulfoton. In addition, there are twenty-one section 24(c) "Special Local Need" registrations.

Ethoprop is a contact soil insecticide-nematicide registered for use on a variety of tropical fruits, vegetables, ornamentals, field crops, commercial turf, and home lawns as listed in Section F.3 below. It is applied as a soil-incorporated, broadcast, or band treatment. It is also used as a root dip treatment for citrus and certain ornamentals.

Ethoprop formulations are commonly applied by using ground equipment and are incorporated into the soil immediately after application with the use of cultivating equipment and/or by irrigation. For the emulsifiable concentrate formulation, spray equipment (i.e., backpack sprayers) and watering cans may be used for application. The specific type of equipment is determined by site and equipment availability.

The emulsifiable concentrate formulations of ethoprop, 40% and greater, are "Restricted Use" pesticides, and applicators must be certified or under the direct supervision of applicators certified to apply these products (44 CFR 45131, August 1, 1979). In addition, granular formulations 10% and greater have been proposed for "Restricted Use" classification on the basis of acute dermal toxicity and avian hazard (44 FR 45218, August 1, 1979). These will be classified in accordance with the optional procedures of 40 CFR 162.30. There are no products for use or storage in or around the home.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on ethoprop, the Agency has made the following determinations:

1. The Agency had identified a potential avian adverse effect concern. Based on acceptable subacute dietary studies, it is calculated that the expected residues on avian foodstuffs following a single application of ethoprop at a rate of 6 pounds a.i. per acre (maximum registered corn rate) exceed the subacute dietary LC_{50} level in avian species. In order to determine whether significant evidence relating to this adverse effect would raise prudent concerns of unreasonable adverse risk to man or the environment, the Agency is requiring

additional avian field testing data. Once the Agency has evaluated these additional data, it will determine whether EPA should initiate a public interim review process by placing the chemical in Special Review. If instead, regulation of the chemical through the normal registration process is found to be appropriate, the Agency will update its regulatory position and rationale to reflect this conclusion and the reasoning behind it.

2. The "Restricted Use" classifications for all ethoprop emulsifiable concentrate formulations containing 40% and greater will continue.

3. Although the Agency is unable to complete a tolerance reassessment because of certain residue chemistry and toxicology data gaps, the Agency concludes that no change in present tolerances are indicated at this time. Further, although the provisional acceptable daily intake has been exceeded, future requests for tolerances will not be automatically rejected on this basis. (Refer to Section H, TOLERANCE REASSESSMENT).

4. No federal or state reentry intervals have been established for ethoprop. There is no need to establish any reentry intervals, since the practice of soil incorporation is expected to minimize exposure during reentry operations. This is also true for turf areas where the pesticide is watered-in.

5. Manufacturing-use pesticide products containing ethoprop as the sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard.

6. Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to permit new ethoprop registrations.

D. REGULATORY RATIONALE

The Agency has determined that it should continue to allow the registration of ethoprop after considering the following:

1. Adequate studies are available to assess the acute toxicological effects of technical ethoprop. Technical ethoprop is in Toxicity Category I on the basis of acute oral, dermal, eye, and inhalation effects. Human hazard precaution statements associated with Toxicity Category I

labeling [40 CFR 162.10(h)(2)(i)] should minimize the acute hazards associated with these routes of exposure for the technical product.

2. No other human toxicological hazards of concern to the Agency have been identified in the studies reviewed for this Standard.

3. Based on residue chemistry and toxicological considerations, there is no evidence to suggest that the current tolerances are likely to expose the public to unreasonable adverse effects.

4. Reported pesticide incidents cited in the Pesticide Incident Monitoring System (PIMS) through November 1982 for ethoprop indicate that in those incidents which were reported with some detail, affected individuals were not wearing appropriate clothing or other protective equipment when exposure occurred.

5. Ethoprop is not expected to contaminate drinking water supplies. It degrades fairly rapidly with half-lives of 3-56 days in soil. Increase in soil temperature tends to increase the dissipation rate. However, ethoprop is very mobile in sandy soil and has a potential for contaminating groundwater in areas of sandy soil with a high water table. Because of this, soil dissipation study monitoring may have to be conducted at a depth greater than 6 inches depending on the leaching data.

6. Based on studies available to assess hazards to wildlife and aquatic organisms, ethoprop is characterized as very highly toxic to birds, marine/estuarine crustaceans, and marine/estuarine fish species. It is moderately to highly toxic to coldwater fish species and moderately toxic to honeybees. Updated label precautions required by this Standard should reduce the hazard to fish and other wildlife. Once data gaps are filled, the potential hazards to terrestrial and aquatic species will be better defined.

7. Under FIFRA the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see Section 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of ethoprop.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this Standard, products must contain ethoprop as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES IN LIMITS

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain ethoprop as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MPs containing ethoprop for any acute toxicity category, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing ethoprop may be labeled for formulation only into end-use products for:

- Terrestrial, non-domestic, food uses on: bananas, beans (dry, snap), cabbage, corn (field and sweet), peanuts, pineapples, plantain, potatoes (white, Irish), soybeans, sugarcane, and sweet potatoes.

- Terrestrial, non-domestic, non-food uses on: citrus seedlings, commercial turf (including bermudagrass, zoysiagrass, St. Augustinegrass, centipedegrass, bahiagrass, fescuegrass, kentuckygrass and bluegrass), ornamentals

(including aglaonema, azalea, boxwood, bromeliads, cacti, caladium, camellia, Cape Jasmine, fern, gardenia, holly, philodendron, pothos, sanservieria, and yew), and tobacco.

- o Domestic outdoor use on: lawns [24(c) registration for commercial applicator use only, FL-800028].
- o Greenhouse non-food use on: ornamentals (as specifed above).

G. REQUIRED LABELING

All manufacturing-use products containing ethoprop must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Use Pattern Statements

The ingredients statement for MPs must list the active ingredient as:

Ethoprop, (O-ethyl S,S-dipropyl phosphorodithioate). . . . _____%.

In addition, all MPs must state that they are intended only for formulation into end-use products for any of the use patterns listed above. (Specify specific sites listed in Use Patterns in Section F.3.) A limiting factor will be the data that support these use patterns. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

2. Precautionary Statements

Labels for all MP products containing ethoprop must bear statements reflecting the acute human toxicity of the compound. Ethoprop is in Toxicity Category I by all routes of exposure. The required precautionary statements associated with Toxicity Category I are specified in 40 CFR 162.10.

In addition to the Toxicity Category I labeling requirements identified above, the following human hazard statement, based on data reviewed by the Agency, must appear on all manufacturing-use product labels:

Poisonous if absorbed through the eye. Do not get in eyes.

The following revised environmental hazard statement must appear on all manufacturing-use product labels:

> This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds or public water unless in accordance with NPDES permit. For guidance contact your Regional Office of the EPA.

Label changes to End-Use Products (EPs) are not required by this Standard; however, based on generic data reviewed by the Agency, the following updated environmental hazard statements will be required for EPs under the Agency's Label Improvement Program.

Granular End-use Products

> This pesticide is toxic to fish and wildlife. Birds feeding in treated areas may be killed. Cover or incorporate granules that are spilled. Do not apply directly to water or wetlands. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Non-Granular End-use Products (Except Domestic Turf)

> This pesticide is toxic to fish and wildlife. Birds feeding in treated areas may be killed. Cover or disc spill areas. Do not apply directly to water or wetlands. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Non-Granular End-use Products (Domestic Turf)

> This pesticide is toxic to fish and wildlife. Birds feeding in treated areas may be killed. Do not apply directly to water or wetlands. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.
>
> This pesticide is toxic to bees exposed to direct treatment. Do not apply this pesticide when bees are actively visiting the treatment area.

With respect to potential hazards to federally endangered/ threatened species, ethoprop is currently being reviewed along with a cluster of other chemicals by the Agency and the Office of Endangered Species (OES).

The Agency may, after review of data to be submitted under this Standard, and consultation with OES, impose additional label requirements.

H. TOLERANCE REASSESSMENT

U.S. tolerances are established for negligible residues of the insecticide-nematicide ethoprop in or on the following raw agricultural commodities; bananas, cabbage, corn grain, corn fodder and forage, cucumbers, fresh corn including sweet corn (kernels plus cob with husk removed), lima beans, lima bean forage, peanuts, peanut hay, pineapples, pineapple fodder and forage, soybeans, soybean forage and hay, sugarcane, sugarcane fodder and forage, and sweet potatoes at 0.02 part per million. These tolerances are published in 40 CFR 180.262. There are no international tolerances nor Codex Maximum Residue Limits (MRLs) for residues of ethoprop.

Presently, it is concluded that the plant metabolism of ethoprop is adequately described. Ethoprop in bean and corn plants is metabolized by hydrolysis following uptake from the soil. The metabolites identified are ethyl propyl sulfide, propyl disulfide, ethyl propyl sulfoxide and water soluble high-boiling phosphoric acids and/or their salts. The only residue of toxicological concern is the parent compound. Consequently, for residue analysis and tolerance reassessment only residues of the parent compound, ethoprop per se, are considered. While metabolism studies are available for bean plants and corn only, quantitative differences rather than different metabolites in the commodities for which negligible tolerances (0.02 ppm) have been established are expected. If, however, future requests are submitted for tolerances at higher than the "negligible" level, additional metabolism data depicting more clearly the residue level of the individual metabolites with respect to the parent compound will be required.

There are no data to indicate how ethoprop is metabolized or excreted by animals. In one feeding study in which dogs were fed unlabeled ethoprop for 21 days at rates up to 2.3 ppm of their diet, no detectable residues (i.e. >0.01 ppm) were found in their tissues. Because feed items with established negligible residue tolerances (<0.02 ppm) are expected to have little, if any, ethoprop residues, it is concluded that the metabolism in animals, although not completely known, is at this time sufficiently detailed. If, at a future date, the establishment of finite tolerances for residues of ethoprop is requested in or on feed items which are significantly higher than the negligible 0.02 ppm level, then more detailed

metabolism studies in a large ruminant will be needed. Presently no tolerances are required for residues which may occur in the products of animals (livestock) used for food.

U.S. tolerances for most raw agricultural commodities are supported by current residue chemistry data. In some cases however, more data are required:

- Data on residues in potatoes reflecting the maximum recommended use of 9 lb. active/acre.

- Data on residues in tobacco reflecting the maximum registered rate. Depending on the residue level found in tobacco, additional data related to that use may be required.

The Provisional Acceptable Daily Intake (PADI) of ethoprop is 0.000075 mg/kg/day. This is based on a rat cholinesterase inhibition* No Observed Effect Level (NOEL) of 0.3 ppm and a Safety Factor (SF) of 200. The Provisional Maximum Permissible Daily Intake (PMDI) is 0.0045 mg/day (based on a 60 kg body weight person). The Theoretical Maximum Residue Concentration (TMRC), based on relevant food factors and established tolerances is 0.0052 mg/day for a 1.5 kg diet. The percent of the PADI utilized is 115.02%.

Although the Provisional Acceptable Daily Intake has been exceeded, it is concluded that exceeding the PADI does not necessarily in and of itself represent an immediate hazard to the public. The actual levels of residues to which the public is exposed are likely to be considerably less than this

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* This study is not considered to be supportive of tolerance registrations, since the experimental design of the study was considered to be inadequate. This study is being retained on an interim basis for the calculation of the PADI since it provides a more conservative PADI in comparison to the PADI calculated for a 90-day dog study (which was found to be acceptable as supporting data for the establishment of tolerances). The NOEL in this study is based upon biologically meaningful results. The presence of uniform and consistent decreased cholinesterase values at consecutive measurement intervals suggested that the NOEL for cholinesterase inhibition in the 90-day rat study may be less than 0.30 ppm but not much greater than 0.30 ppm.

theoretical maximum would indicate for some of the following reasons:

- Not every crop for which a tolerance has been established is treated with the pesticide.
- Most treated crops have residue levels which are below the established tolerance level.
- Processing or time to market often result in further residue reductions.
- Preparing food for consumption often results in residue reductions.
- Not all crops contributing to the TMRC (PADI) are likely to be consumed by an individual.
- Market basket surveys conducted by FDA indicate that little if any real pesticide residues of organophosphates actually remain in/on finished foods.

After review of the requested toxicology data, the ADI will be reevaluated.

A correction to the ethoprop tolerances is:

- 40 CFR 120.262. The tolerance should be revised to read: pineapples, pineapple fodder and forage, instead of pineapple fodder and forage.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines [2/], or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	GS0106009	No
61-2 - Statement of Composition	TGAI	Yes	GS0106009	No
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	GS0106009	No
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No		Yes[3/]
62-2 - Certification of Limits	TGAI	No		Yes
62-3 - Analytical Methods for Enforcement Limits	TGAI	Partial	GS0106006 GS0106009	Yes[4/9/]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0106009	No
63-3 - Physical State	TGAI	Yes	GS0106009	No
63-4 - Odor	TGAI	Yes	GS0106009	No
63-5 - Melting Point	TGAI	Not Applicable	-	-

*Data submitted by Mobil Chemical Co and subsequently transferred to Rhone-Poulenc Chemical Co., the current data owner. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
Physical and Chemical Characteristics				
63-6 - Boiling Point	TGAI	Yes	GS0106009	No
63-7 - Density, Bulk Density or Specific Gravity	TGAI	Partial	GS0106009	Yes[5/]
63-8 - Solubility	TGAI OR PAI	Partial	GS0106009 GS0106036	Yes[5/9/]
63-9 - Vapor Pressure	TGAI OR PAI	Yes		No
63-10 - Dissociation constant	TGAI OR PAI	Not Applicable	-	
63-11 - Octanol/water partition coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		No[7/]
63-13 - Stability	TGAI	Yes	GS0106009	No
Other Requirements:				
64-1 - Submittal of samples	TGAI	No		No[8/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than June 1986.
3/ All impurities and their percent by weight (upper limits) in the final technical product, present at >0.1% must be identified. A confidential statement of ingredient should be submitted reflecting recent procedures for manufacturing ethoprop.
4/ Raw data and techniques used to identify the impurities in the technical product must be submitted.
5/ No temperature was reported for the specific gravity. This constitutes a data gap.
6/ The solubility data should be expressed in terms of g/100ml of solvent at 20°C or in terms such as ppm. The data should also indicate the temperature at which the test was performed.
7/ Since ethoprop is practically insoluble in water, no pH is required.
8/ Submittal of samples is not required.
9/ All data citations are required to support the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	GS0106026 GS0106027 GS0106028 GS0106029 GS0106030 GS0106031 GS0106032	No[3/ 12]
- Livestock	PAIRA and plant metabolites	Partial	GS0106034*	No[4/]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	GS0106011 GS0106012 GS0106013	No[12/]
- Animal residues	TGAI and metabolites	No		No[5/]
171-4 - Storage Stability Data	PAI	No		No[6/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliograph Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Cereal Grains				
° Corn (Dried field corn, fresh sweet corn)	TEP	Yes	GS0106014 GS0106015	No[12/]
Forage, Fodder and Straw of Cereal Grains				
° Corn (Dried field corn, fresh sweet corn)	TEP	Yes	GS0106014 GS0106015	No[12/]
Root and Tuber Vegetable Crops				
° Potatoes	TEP	Partial	GS0106023*	Yes[7/]
° Sweet Potatoes	TEP	Yes	GS0106025*	No
Fruiting Vegetables (Cucurbits) Group				
° Cucumbers	TEP	Yes	GS0106022*	No
Brassica (Cole) Leafy Vegetables Group				
° Cabbage	TEP	Yes	GS0106021*	No

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue- (continued)				
Legume Vegetables (Succulent or Dried) Group				
° Soybeans	TEP	Yes	GS0106017 GS0106018	No[12/]
° Beans (Snap and Lima)	TEP	Yes	GS0106024*	No
Foliage of Legume Vegetables Group				
° Soybean forage and hay	TEP	Yes	GS0106016	No
° Bean forage (snap and lima)	TEP	Yes	GS0106024*	No
Miscellaneous Crops				
° Sugarcane, sugarcane fodder and forage	TEP	Yes	GS0106020*	No
° Peanuts and peanut hay	TEP	Yes	GS0106019	No
° Pineapple, pineapple fodder and forage	TEP	Yes	GS0106034*	No
° Bananas, plantain	TEP	Yes	GS0106035* GS0106033*	No[12/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue (continued)				
Residues in Tobacco	TEP	No		Yes[8/]
Residues in Processed Commodities	Residue-bearing Raw Agricultural Commodities			
°Corn	-do-	No		No[9/]
°Peanuts	-do-	No		No[9/]
°Pineapple	-do-	No		No[9/]
°Potato	-do-	Reserved[10/]		
°Soybeans	-do-	No		No[9/]
°Sugarcane	-do-	No		No[9/]
°Sweet potatoes	-do-	No		No[9/]
171-4 - Magnitude of the Residue in Food Producing Animals				
°Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partial	GS0106010	No[11/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

§158.125 Residue Chemistry

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted no later than June 1986.
3/ While only metabolism studies are submitted for bean plants and corn, we would expect only quantitative differences rather than different metabolites in the commodities for which negligible tolerances (0.02 ppm) have been established. If future requests are submitted for tolerances at higher than the "negligible" level, additional metabolism data depicting more clearly the residue level of the individual metabolites in respect to that of the parent compound will be required.
4/ No data on the metabolism of ethoprop in ruminants, non-ruminants and poultry are available. Further, no metabolites of ethoprop in animals have been identified. It is understood that the metabolites are the same as those identified in plants. Because feed items with established negligible residue tolerances (<0.02 ppm) are expected to have little, if any, ethoprop residue, no further data are required at this time. If, at a future date, the establishment of finite tolerances for residues of ethoprop is requested in or on feed items which are significantly higher than the negligible 0.02 ppm level, then more detailed metabolism studies in a large ruminant will be needed.
5/ No methodology for the collection of animal residues are needed.
6/ Some residue storage data are required to indicate the potential for the loss of residues between sampling and analysis
7/ Data are needed reflecting the maximum recommended rate of 9 lbs. A.I./Acre.
8/ Data reflecting the residue level as a function of the maximum registered use on tobacco must be submitted. Data submitted must show conclusively the level of residue likely to result from the use of the pesticide. Pyrolysis products derived from the active ingredient must be characterized if residues at 0.1 ppm or more are detected.
9/ Because the residue situation in the raw agricultural commodity is essentialy a "no residue" one, residues in processed commodities would be expected to be less than the established tolerance of 0.02 ppm. No processing study is required.
10/Reserved pending fulfillment of data gap on the raw agricultural commodity.
11/Based on the premise that feed items of ruminants, poultry and non-ruminants contain only negligible ethoprop residues (<0.02 ppm) it is concluded thast residues will not transfer to meat, milk, poultry meat or eggs. No tolerances are necessary. If a request is made in the future for the establishment of a tolerance for residues higher than that presently established (negligible 0.02 ppm level) involving feed items, we will need a large ruminant and a poultry feeding study indicating the tendency of transfer of residues of ethoprop to meat, poultry meat and eggs.
12/All data citations are required to support the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,F,H	No		Yes
Photodegradation					
161-2 - In Water	TGAI or PAIRA	A,B	No		Yes[4/]
161-3 - On Soil	TGAI or PAIRA	A,B	No		No[5/]
161-4 - In Air	TGAI or PAIRA	A,B	No		No[6/]
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F,H	Partially	00057209 00046721*	Yes[7/11/]
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B	No		Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	Not Applicable	-	-
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	Not Applicable	-	-
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,F,H	Partially	00040382*	Yes[8/]
163-2 - Volatility (Lab)	TEP	A,B,F	No	-	No[6/]
163-3 - Volatility (Field)	TEP	A,B,F	No	-	No[6/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
DISSIPATION STUDIES - FIELD:					
164-1 - Soil	TEP	A,B,H	No		Yes [12]
164-2 - Aquatic (Sediment)	TEP	-	Not Applicable	-	-
164-3 - Forestry	TEP	-	Not Applicable	-	-
164-4 - Combination and Tank Mixes			Not Applicable	-	-
164-5 - Soil, Long-term	TEP	A,B	No	-	No [9]
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Combined)	PAIRA	A,B	No	-	Yes
165-2 - Rotational Crops (Field)	TEP	A,B	Reserved [10]		
165-3 - Irrigated Crops	TEP	-	Not Applicable		
165-4 - Fish	TGAI or PAIRA	A,B	No		Yes
165-5 - In Aquatic Non-Target Organisms	TEP	-	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3/ Data must be submitted no later than June 1986.
4/ Although ethoprop is incorporated into the soil immediately after application, this study along with a hydrolysis study, is required in order to determine whether significant amounts of ethoprop will reach the aquatic environment when the pesticide is used according to label directions.
5/ This study is waived, because of the practice of soil incorporation.
6/ This study is not required, since ethoprop has a low vapor pressure.
7/ Identification of degradates must be provided.
8/ Need aged study and other representative soils.
9/ This study is required only if the aerobic soil metabolism study described in 162-1 demonstrates that for field and vegetable crop use, the total of pesticide excluding bound residues in soil is greater than 50% of the amount of pesticide initially applied at the time when a subsequent application would occur.
10/ Reserved pending results of 165-1.
11/ All data citations are required to support the data requirement.
12/ Based on leaching data, soil may have to be sampled to a depth greater than 6 inches.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,F,H	Yes	00078035	No
81-2 - Dermal LD_{50}	TGAI	A,B,F,H	Yes	00078035	No
81-3 - Inhalation LC_{50}- Rat	TGAI	A,B,F,H	Yes	GS0106008*	No
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,F,H	Partial	GS0106007*	No[4/]
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A	Partial	00075240	Yes[5/]
82-2 - 21-Day Dermal	TGAI	B	No		Yes
82-3 - 90-Day Dermal	TGAI		Reserved[6/]		
82-4 - 90-Day Inhalation - Rat	TGAI		Reserved[7/]		
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI		No		No[8/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,F,H	No		Yes[9/]
83-2 - Oncogenicity Study- 2 species: Rat and Mouse preferred	TGAI	A,B,F,H	No		Yes[11/]
83-3 - Teratogenicity - 2 species	TGAI	A,B,F,H	Partial	00104532	Yes[10/]
83-4 - Reproduction, 2-generation	TGAI	A,B,F,H	No	-	Yes[11/]
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B,F,H	No		Yes
84-2 - Chromosomal Aberration	TGAI	A,B,F,H	No		Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,F,H	No	-	Yes
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA		No		Yes
85-2 - Domestic Animal Safety	Choice		Not Applicable	-	-

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

§158.120 Toxicology
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient.
2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food Crop; C= Aquatic, Food Crop D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3/ Data must be submitted no later than June 1986.
4/ Even though the study was conducted using Mocap® 6EC (70%) and not the technical grade of the active ingredient, this study will suffice to fulfill this requirement.
5/ The 90-day dog feeding study is acceptable. A new 90-day subchronic rat feeding study must be submitted.
6/ Reserved pending results of 82-2 (21-day dermal).
7/ Reserved pending submission and results of residue data on tobacco.
8/ Not required since delayed neurotoxicity test does not show neurotoxicity.
9/ A 1-year or longer dog study and rat chronic feeding study is required. The rat chronic feeding study is to be completed by February 1985, in accordance with the 3(c)(2)(B) Data Call-In Notice issued February 4, 1981.
10/ A teratology study in rabbits is required. This study is to be completed by April 1983, in accordance with the 3(c)(2)(B) Data Call-In Notice issued February 4, 1981.
11/ These studies are to be completed by February 1985, in accordance with the 3(c)(2)(B) Data Call-In Notice issued February 4, 1981.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B,F,H	No		No[4/]
132-1 - Soil Dissipation	TEP	A,B,F,H	No		No[4/]
133-3 - Dermal Exposure	TEP	A,B,F,H	No		No[4/]
133-4 - Inhalation Exposure	TEP	A,B,F,H	No		No[4/]

1/ Compositition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
4/ Not required because of practice of soil incorporation and watering-in.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	Yes	00092147* 05008363 GS0106004	No[11/]
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	00022923	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,H	No		No[3/]
71-4 - Avian Reproduction	TGAI	A,B,H	Reserved[5/]		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,H	Partial	00092113* GS0106005*	Yes[6/11/]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,H	Partial	GS0106001	Yes[7/]
-do-	TEP	A,B,H	Partial	GS0106002 00048777*	No[8/]
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	No		Yes[9/]
-do-	TEP	A,B,H	Partial	GS0106003	No[8/]

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use[2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.145 Wildlife and Aquatic Organisms (continued)					
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,H	Partial	00092111* 00066341	Reserved[10/ 11/]
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,H	Partial	00066341	Reserved[10/]
72-5 - Fish Life-Cycle	TGAI	A,B,H	No		No[3/]
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A,B,H	Reserved[10/]		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B,H	Reserved[10/]		

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TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical Grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Crop; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3/ These data are not normally required.
4/ Data must be submitted no later than June 1986.
5/ Reserved pending submission of appropriate environmental fate data needed; such as field dissipation studies to better define expected residues on vegetable and soil for both crop and turf use.
6/ At this time two acute field studies need to be performed: one for use of the granular product on a field crop and another for use of the EC on turf grasses. Maximum application rates should be tested. Exact protocols must be approved by the Agency prior to study initiation. Depending on results from the two initial studies, a third may have to be performed using the granular on turf.
7/ The requirement for a study on a coldwater fish species is fulfilled. Data are needed for a warmwater species.
8/ Not applicable to this Manufacturing-Use Standard.
9/ The study reviewed was found to be unacceptable, since it did not report the % a.i. of the test material.
10/ Reserved pending the submission of the acute toxicity data on a warmwater fish species and a freshwater aquatic invertebrate along with appropriate environmental fate information (for example, hydrolysis and photolysis in water). These data are needed to determine if hazardous concentrations of ethroprop will reach the aquatic environment when products are used as directed.
11/ All data citations are required to support the data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No		No[4/]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No		No[4/]
122-1 - Vegetative Vigor	TGAI		No		No[4/]
122-1 - Aquatic Plant Growth	TGAI		No		No[4/]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No		No[4/]
123-1 - Vegetative Vigor	TGAI		No		No[4/]
123-2 - Aquatic Plant Growth	TGAI		No		No[4/]
TIER III					
124-1 - Terrestrial Field	TEP		No		No[4/]
124-2 - Aquatic Field	TEP		No		No[4/]

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food Crop; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F=Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than _____.

4/ These requirements are generally waived unless it is believed there is a phytotoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR ETHOPROP

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No		No[3/]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No		No[3/]
122-1 - Vegetative Vigor	TGAI		No		No[3/]
122-1 - Aquatic Plant Growth	TGAI		No		No[3/]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No		No[3/]
123-1 - Vegetative Vigor	TGAI		No		No[3/]
123-2 - Aquatic Plant Growth	TGAI		No		No[3/]
TIER III					
124-1 - Terrestrial Field	TEP		No		No[3/]
124-2 - Aquatic Field	TEP		No		No[3/]

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food Crop; C= Aquatic, Food Crop D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I=Indoor.

3/ These requirements are generally waived unless it is believed there is a phototoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR EPTC

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	-	A,B,H	(Reserved)[8/]		
142-2 - Aquatic insect life-cycle study	-	A,B,H	(Reserved)[8/]		
142-3 - Simulated or actual field testing for aquatic insects	-	A,B,H	(Reserved)[8/]		
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	-	A,B,H	(Reserved)[8/]		

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3/ Data must be submitted no later than June 1986.
4/ Data required because acute test showed contact LD_{50} of less than 11 micrograms per bee.
5/ Required only if product is intended for foliar application to seed alfalfa.
6/ Reserved pending development of test methodology.
7/ May be required under the following conditions.
(i) Data from the honey bee subacute feeding study (§141-4) indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);
(ii) Data from residual toxicity studies (§§141-2 and 141-4) indicate extended residual toxicity; or
(iii) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity such as the ability to cause reproductive or chronic effects.
8/ Reserved pending decision as to whether data requirement should be established.
9/ Either data citation may be cited to support this data requirement.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	MP	Yes	GS0106009	No
61-2 - Statement of Composition	MP	Yes	GS0106009	No
61-3 - Discussion of Formation of Ingredients	MP	Yes	GS0106009	No
Analysis and Certification of Product				
62-1 - Preliminary Analysis	MP	No		Yes[3/]
62-2 - Certification of Limits	MP	No		Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	Partial	GS0106009	Yes[4/]
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	GS0106009	No
63-3 - Physical State	MP	Yes	GS0106009	No
63-4 - Odor	MP	Yes	GS0106009	No
63-7 - Density, bulk density, or specific gravity	MP	Partial	GS0106009	Yes[5/]
63-12 - pH	MP	No		No[6/]

*Data submitted by Mobil Chemical Co. and subsequently transferred to Rhone-Poulenc Chemical Co., the current data owner. These data may be compensable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.120 Product Chemistry (continued)				
63-14 - Oxidizing or reducing action	MP	Yes	GS0106009	No
63-15 - Flammability	MP	No		Yes[7/]
63-16 - Explodability	MP	No		Yes
63-17 - Storage Stability	MP	Yes	GS0106009	No
63-18 - Viscosity	MP	No		Yes
63-19 - Miscibility	MP	No		Yes
63-20 - Corrosion	MP	No		Yes
Other Requirements				
64- 1 - Submittal of Samples	MP	Reserved[8/]		

*Data submitted by Mobil Chemical Co. and subsequently transferred to Rhone-Poulenc Chemical Co., the current data owner. These data may be compensable.

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted no later than December 1983.

3/ All impurities and their percent by weight (upper limits) in the final product, present at >0.1% must be identified. A confidential statment of ingredient should be submitted reflecting recent procedures for the manufacturing of ethoprop.

4/ Raw data and techniques used to identify the impurities in the technical product must be submitted.

5/ No temperature was reported for the specific gravity. This constitutes a data gap.

6/ Since ethoprop is insoluble in water, no pH is required.

7/ Data should be submitted indicating whether or not ethoprop is combustible. If it is combustible, a flashpoint should be reported.

8/ The Agency will require a sample later if need arises.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ETHOPROP

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00078035	No
81-2 - Dermal LD_{50}	MP	Yes	00078035	No
81-3 - Inhalation LC_{50} - Rat	MP	Yes	GS0106008*	No
81-4 - Primary Eye Irritation - Rabbit	MP	Partial	00078036	No[3/]
81-5 - Primary Dermal Irritation	MP	Partial	00048774*	No[4/]
81-6 - Dermal Sensitization	MP	No		Yes

*Data submitted by Mobil Chemical Company and subsequently transferred to Rhone-Poulenc Chemical Co., the current data owner. These data may be compensable.

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted no later than December, 1983.

3/ Study classified as supplemental, but need not be repeated since a new study would probably not yield any additional information (Toxicity Category I).

4/ A primary irritation index was not calculated since death occurred before the manifestation of any signs of skin irritation. This study does not need to be repeated (Toxicity Category I).

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. William H. Miller
Product Manager 16
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-2600

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet". Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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GS0106017 Mobil Chemical Co. (1969) Mocap Residues in Soybeans. (Unpublished study received 8/29/69 under 9F0872; CDL:RCB-116228.)

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GS0106031 Mobil Chemical Co. (1968) Gas Chromatography of Mocap metabolites. (Unpublished study received 9/4/68 under 9F0750; prepared by the U. of Maryland, College Park, MD; CDL:RCB-115725.)

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GS0106034 Mobil Chemical Co. (1970) Residues of Mocap in Pineapples, Forage, and Fodder. (Unpublished study received 3/30/70 under 0F0959; CDL:RCB-116580.)

GS0106035 Mobil Chemical Co. (1970) Mocap Residues in Bananas. (Unpublished study submitted 3/30/70 under 0F0959; prepared by Compania Bananera Atlantica, San Jose, Costa Rica; CDL:RCB-116581.)

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

Appendix IV-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (nydrate)
Chlordane (technical)
Chlorobenzene
4-Cnloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metneno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (nexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Napnthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Metnyl alcohol (methanol)
Methyl ethyl ketone
Metnyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Ethoprop as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s).

Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

William H. Miller, Product Manager 16
Environmental Protection Agency
Registration Division (TS-767)
Office of Pesticide Programs
Washington, D.C. 20460
Telephone 703/557-2600

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Reg. No.	Product Name

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufactucturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).